

EXHIBIT K

BRINGING SCIENCE TO BEAR ON OPIOIDS

Report and Recommendations from the ASPPH Task Force
on Public Health Initiatives to Address the Opioid Crisis

November 2019



Association of Schools and Programs of Public Health

The Association of Schools and Programs of Public Health (ASPPH) is the voice of accredited academic public health, representing more than 120 schools and programs accredited by the Council on Education for Public Health (CEPH). The Association of Schools and Programs of Public Health (ASPPH) is a 501c3 membership organization headquartered in Washington, DC.

The Association's mission is to strengthen the capacity of its members by advancing leadership, excellence, and collaboration for academic public health. The ASPPH's Strategic Framework 2020 calls for the Association to advocate for public health education, research, practice and the public's health by championing the engagement of academic public health and the use of evidence-based science — across all professions and sectors — to solve the critical challenges facing our communities.

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The Association of Schools and Programs of Public Health (ASPPH), representing more than 120 institutions accredited by the Council on Education in Public Health, has a key strategic objective to “Champion the engagement of academic public health and the use of evidence-based science — across all professions and sectors — to solve the critical challenges facing our communities.” The sharp increase in the prevalence of opioid use disorder in the United States is exactly the type of critical challenge that demands the engagement of academic public health faculty as well as the use of evidence in related policy initiatives.

In late 2018, the ASPPH Board of Directors formed a Task Force on Public Health Initiatives to Address the Opioid Crisis, composed of recognized experts in the field, from both within the ASPPH membership as well as from related academic fields. The Task Force was charged with defining “public health approaches” for the prevention and treatment of opioid use disorder and the mitigation of other consequences of opioid use; describing how such approaches should be assessed and clarifying for policy makers why such approaches are essential and how they complement other policy initiatives that address harmful substance use; and, identifying a range of initiatives that reflect such an approach.

After much deliberation, an extensive review of the scientific literature, consultation with other experts, and the practical experience of Task Force members, the panel developed the findings and recommendations that follow. They have been reviewed and endorsed by the ASPPH Board of Directors.

The Task Force’s dozens of recommendations include proposed policy changes that may require legislative or regulatory action, investments by governmental entities, or changes in business practices by opioid manufacturers, distributors, and prescribers. Many of the recommendations will help inform the parties to opioid-related legal actions and others will be part of the Association’s advocacy agenda going forward.

We are grateful to members of the Task Force for their efforts and the seriousness with which they undertook their charge. We believe the Task Force’s recommendations, if implemented and adequately resourced, will help advance the treatment of people currently suffering from opioid use disorder, greatly reduce the number of citizens misusing opioids in the future, and begin to heal communities devastated by the opioid crisis.



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Executive Summary

The statistics about the opioid crisis in the United States are startling:

- More Americans die each year from opioid overdoses than died in any armed conflict since the end of World War II.¹
- On average, 130 Americans die each day from an opioid overdose.²
- Overdose is now the leading cause of unintentional injury death in the United States, surpassing motor vehicle deaths.³

Alarmed by these statistics and knowing that the public health profession has a responsibility to address this crisis, the Association of Schools and Programs of Public Health assembled an expert Task Force in late 2018. After many months of research, consultation, and discussion, the Task Force has compiled the comprehensive set of recommendations laid out in this document. These recommendations rest on the foundational beliefs that the opioid crisis is a public health issue that touches all levels of society and must be addressed across sectors; that opioid use disorder is a chronic, relapsing brain disease; that inappropriate use of opioids leading to addiction was driven by corporate and personal greed; and that evidence-based public health approaches can reduce the harms of this epidemic and help bring it to an end.

If a master settlement agreement is reached in the multi-district litigation currently pending, funds should be used not only to compensate states and communities for expenditures related to the epidemic, but also to prevent it from spreading, ameliorate associated harms, and contain related syndemics (synergistic epidemics of two or more conditions with related underlying causes). The Task Force recommends the use of those monies specifically to:

- Improve the collection of evidence and epidemiological data on all dimensions of the opioid epidemic
- Combat stigma
- Ensure access to medications for opioid use disorder
- Reduce associated harms
- Support primary prevention efforts
- Fund research, and
- Advance program evaluation and implementation science

The Task Force also recommends several legislative and regulatory reforms to be incorporated into the ASPPH advocacy agenda to prevent further inappropriate lobbying, marketing, and prescribing of these highly addictive substances; and to increase access to harm reduction services.

¹ National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse; Phillips JK, Ford MA, Bonnie RJ, editors. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*. Washington (DC): National Academies Press (US); 2017 Jul 13. 4, Trends in Opioid Use, Harms, and Treatment. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK458661/>

² Centers for Disease Control and Prevention. <https://www.cdc.gov/drugoverdose/epidemic/index.html> Accessed September 12, 2019.

³ Case, A., Deaton, A. (2017). Mortality and morbidity in the 21st century. Brookings papers on economic activity, 2017, 397.

The current state of the opioid crisis warrants a comprehensive, multi-part federal effort that combines primary medical care, essential support services, outreach to persons who misuse substances, patient engagement, and access to medications for opioid use disorder (OUD). The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act is an excellent example of such an effort and should serve as a model.

The death toll is mounting. Nationwide, we must marshal financial resources, legislative power, knowledge, inquiry, and expertise to combat the opioid crisis, and turn the tide.

Recommendations

Evidence and Epidemiology

- Implement improved metrics on all dimensions of the epidemic
- Create a national open data-sharing center on substance use
- Leverage national computational research resources for sophisticated data science approaches to risk mitigation
- Standardize, use, and expand rigorous observational epidemiological surveillance tools
- Enhance harm reduction programs
- Detect fentanyl and related analogs
- Expand public messaging about evidence-based harm reduction programming
- Further expand and support naloxone distribution efforts
- Fund a robust research and evaluation program that focuses both on effectiveness and the impact of harm reduction interventions on individuals and communities

Anti-Stigma and Harm Reduction

- Mount a national anti-stigma campaign around opioid use disorder and its treatment
- Develop and implement anti-stigma training programs for all professionals likely to come into contact with persons with opioid use disorder and those seeking treatment for it
- Reduce barriers to prescribing medications for opioid use disorder and ensure that they are widely available
- Systematically elevate the voices and tell the stories of people who use drugs and those in recovery
- Train and deploy peer support specialists and navigators
- Create and promote a robust national information exchange on harm reduction and evidence-based harm reduction programming
- Scale up syringe exchange programs
- Establish legal supervised injection facilities in areas of high need
- Establish and support an independent entity to develop targeted programs and initiatives to increase public awareness of the risks of opioid misuse and opioid use disorder and to promote primary prevention at the population level
- Support formal public health training programs at schools and programs of public health focused on OUD
- Create and implement expanded, credible prescriber and dispenser training by one or more independent organizations
- Underwrite extensive academic detailing and counter-detailing on opioids
- Create and implement collaborative models with law enforcement
- Develop and implement evidence-based law enforcement policies, including police practices directed at drug users
- Promote drug disposal and create additional and more diverse disposal sites

Primary Prevention

Access to Medications for Opioid Use Disorder

- Facilitate local access to MOUD
- Deregulate buprenorphine prescribing
- Maximize the use of telemedicine
- Suspend the need for X waivers
- Extend training to pharmacists to identify and treat people with OUD
- Encourage and leverage partnerships among prevention specialists, treatment providers, corrections personnel, and law enforcement to ensure continuity of care for opioid use disorder upon discharge from jail, prison, or drug court

Research

- Understand the causes and remedies for the psycho-social drivers of the substance use epidemic
- Conduct dissemination and implementation studies to expand collaborations between health and law
- Study the expansion of access to medication-assisted treatment, as well as other forms of treatment for OUD
- Conduct computational modeling and simulation
- Investigate the biology and sociology of opioid use disorder
- Study clinical decision support tools to better equip healthcare providers to treat these patients and to integrate treatment into mainstream healthcare

Evaluation and Implementation Science

- Establish a multi-site, multi-institutional collaborative evaluation structure that will leverage the strengths of different universities and agencies toward an effective, coordinated approach
- Develop new and innovative evaluation methodologies

Regulatory and Legislative Reforms

- Modify FDA review and approval of applications for pain medications to focus on the risks and benefits to public health
- Discontinue the promotion of opioids for long-term use for chronic non-cancer pain except for palliative and end-of-life care
- Adopt the recommendations of the National Academies of Sciences for a revised cost-benefit framework to guide the approval of novel opioid products or the removal from the market of existing opioid products
- Approve an affordable, accessible form of naloxone that can be sold over the counter
- Impose post-market requirements on opioid manufacturers, including the development of risk evaluation and mitigation strategies
- Pass Congressional legislation to enact a comprehensive program using the Ryan White CARE Act as a model
- Modernize and resource data and sentinel surveillance programs
- Modernize DATA 2000 to eliminate the X waiver
- End the legislative prohibition on the purchase of syringes with federal funds
- Support the availability of supervised consumption sites
- Ensure that federal healthcare plans cover a full range of alternative pain management programs

Industry Changes

- Voluntarily end all lobbying and marketing activities related to opioids and other drugs of potential abuse
- Fund aggressive, independent campaigns aimed at educating the public about the risk of opioids and the availability of treatment options

I. Introduction

Since the late 1990s, the United States has experienced a sharp increase in the prevalence of opioid use disorder (OUD), which has led to record high levels of drug overdose deaths and an array of health and social problems. Opioid overdose deaths, once rare, have surpassed motor vehicle crashes as the leading cause of accidental death in the United States,¹ following decades of year-on-year increases in overdose death rates.² In 2017, there were 47,600 opioid-related drug overdose deaths.³ The increased prevalence of opioid use disorder has also been associated with rising rates of neonatal abstinence syndrome, children entering foster care, injection-related acute and chronic infectious diseases, increased arrest and incarceration for crimes driven by OUD, and a negative impact on productivity and workforce participation. Major legislative and policy initiatives to address the crisis have focused almost exclusively on expanding treatment options, developing new therapies and therapeutics to address intractable pain, and the interdiction of illegal drug supplies.⁴ A comprehensive set of evidence-based public health-focused initiatives is urgently needed to guide interventions to ameliorate the epidemic, reduce the death toll, and bring the crisis to an end.

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From 1999 until 2010, the increase in OUD and opioid-related overdose deaths paralleled a sharp increase in the prescribing of opioid analgesics. The medical community became more aggressive in its use of opioids in response to a multi-faceted pharmaceutical industry-funded campaign that downplayed opioid risks and exaggerated benefits.⁵ Recognition that the opioid crisis was caused largely by deceptive marketing has led more than 40 states and hundreds of local, territorial, and tribal governments to file claims seeking funds from the opioid industry to abate the crisis they have caused. Dan A. Polster, District Judge of the U.S. District Court for the Northern District of Ohio, who is presiding over multi-district litigation filed by hundreds of counties, wrote in a ruling: “It is accurate to describe the opioid epidemic as a man-made plague, twenty years in the making. The pain, death, and heartache it has wrought cannot be overstated.”⁶

“Though they are based on diverse legal doctrines and statutory claims, these lawsuits all similarly rely on the theory that governments are spending billions of dollars to address an opioid epidemic that is, at least in large part, caused by the misconduct of the defendants—and the defendants should therefore be responsible for reimbursing those costs,” wrote Micah Berman, an associate professor of public health and law at The Ohio State University’s College of Public Health and Michael E. Moritz College of Law.⁷

One such case, brought by Oklahoma attorney general Mike Hunter, was partially settled between the state of Oklahoma and Purdue Pharma for \$270 million in March 2019⁸, and against Teva Pharmaceutical Industries for \$85 million in May 2019.⁹ In August 2019, Judge Thad Balkman, of the Cleveland County District Court in Norman, Oklahoma, found Johnson & Johnson guilty of being a public nuisance, ordering the pharmaceutical company to pay a fine of \$572 million.¹⁰ As other cases progress through the court system, there are reports of ongoing settlement talks between the parties. Several settlement conferences have been scheduled. As those occur, inevitable comparisons are being drawn between this class action and the earlier litigation and settlement with tobacco manufacturers that resulted in a historic master settlement agreement (MSA) in 1998.^{11,12} Although the

tobacco settlement required manufacturers to pay more than \$200 billion over the first 25 years to the settling states, the settlement is widely regarded as a failure relative to its potential to have impact on tobacco-related morbidity and mortality, due to a provision in the settlement that allowed for state legislative control over the settlement dollars. That is in part a result of the fact that the cause of action against the tobacco industry was to recompense states for costs already expended through Medicaid caring for those with tobacco-related diseases.¹³

Tension between the state attorneys general and their respective state legislatures resulted in a tug-of-war for tobacco MSA funds, only a small percentage of which have been spent on public health initiatives to reduce smoking and tobacco-related deaths,¹³ even though those initiatives have been shown to be effective in reducing youth smoking¹⁴⁻¹⁶ and are cost efficient.¹⁷ “[T]he operative provisions of the MSA did not include any binding provisions that required the states to use the funds — or any portion thereof — to fund tobacco prevention and cessation,” Berman writes.⁷ According to the Campaign for Tobacco-Free Kids, the states will collect more than \$27 billion in fiscal year 2019, but will spend less than 3 percent on prevention and cessation programs.¹⁸ Further, the lack of strategic engagement and partnership with state and local public health authorities prevented strategic deployment of the limited funds made available for public health initiatives.

In a recent op-ed, U.S. Senators Dick Durbin (D-IL) and Sherrod Brown (D-OH) issued a warning: “The diversion of yesterday’s tobacco settlement funds to purposes totally unrelated to public health should be a cautionary tale. If the industries that fueled this [opioid] crisis are held to account for the damage they have caused, their restitution should be devoted to helping our nation heal.”¹⁹

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The tobacco settlement should not serve as a model for the opioid cases. In the event of an MSA with opioid manufacturers and distributors, the leaders and members of the Association of Schools and Programs of Public Health (ASPPH) urge the responsible use of resulting funds for evidence-based public health-focused initiatives directed at ending the OUD epidemic, reducing drug overdose deaths, and preventing a future, similar epidemic, rather than creating a slush fund for myriad pet projects unrelated to this pressing epidemic.

Compared to the distal consequences of tobacco use (which is still the leading cause of preventable morbidity and mortality in the nation), the proximal consequences of the current opioid use disorder epidemic are more acute. The tremendous expansion of the supply of powerful (high-potency as well as long-acting) prescription opioids led to scaled increases in prescription opioid dependence, and the transition of many to illicit opioids, including fentanyl and its analogs, which have subsequently driven exponential increases in overdose.^{2,20} Associated effects of OUD are far-reaching in their public health and social impacts. Policy makers must do better than what was done with the tobacco settlement resources, by requiring responsible stewardship to ensure the dedication of funds not only to compensate states and communities for the incurred and recurring costs of the opioid epidemic, but also to prevent it from spreading, ameliorate associated harms, and contain related syndemics (the aggregation of two or more concurrent or sequential epidemics or disease clusters in a population

with biological interactions)²¹ such as other substance use disorders, criminal legal system involvement, HIV, infective endocarditis, and hepatitis B and C.

“The trajectory of [this] major public health [problem] could be altered by reducing industry manipulation of science and lobbying for policies against the public interest; compensating public coffers for money spent combating these epidemics and redirecting funds to prevention; and using public education, product warnings, and price increases to reduce use of harmful products,” wrote Cheryl Heaton, DrPH, in her September 2018 commentary in the *New England Journal of Medicine*.¹¹

ASPPH and its members have repeatedly called on policy makers to support “public health approaches” to address the opioid use disorder and overdose crisis. In response, representatives from ASPPH member schools and programs, organized and operating as a Task Force, have taken this opportunity to:

- Identify and define evidence-based public health initiatives for the prevention and treatment of OUD, the mitigation of other consequences of opioid use (e.g., hepatitis B and C, HIV, endocarditis, and other diseases), and in consideration of related and emerging substance use problems (e.g., methamphetamine, benzodiazepines, and others) that might be undertaken with revenue resulting from litigation brought by public-sector entities (states, territories, tribes, cities, or localities) against opioid manufacturers and distributors, as well as any other agreements reached pursuant to similar litigation; and
- Elucidate why such approaches are essential and how they complement other policy initiatives that address harmful substance use.

These recommendations are made within the context of the following foundational principles, upon which Task Force members have agreed:

- The opioid crisis is a public health issue that must be addressed in many diverse sectors including healthcare, the criminal legal system, workforce, and economic and community development;
- Opioid use disorder (i.e. addiction) is a chronic, relapsing brain disorder characterized by continued substance use despite negative consequences;
- The opioid crisis was largely caused by a multi-faceted pharmaceutical industry marketing campaign that minimized opioid risks, encouraged aggressive use, and led to a dramatic increase in opioid prescribing;
- Social determinants of health, such as racial/ethnic and economic disparities in access to care, and corporate determinants of health, such as deceptive marketing of pharmaceutical products, must be addressed to solve the problem;
- It is crucial that related policies and programs be aligned with guiding principles of public health, such as the primacy of health and well-being for individuals and communities; dignity for all affected; equality of access; and respect for diverse values, cultures, and beliefs;²²
- Resources gleaned from criminal actions or settlements should be used to mitigate the opioid epidemic and prevent similar crises from occurring in the future; and
- The scale of the synergistic epidemics of OUD, hepatitis B and C, HIV, and suicide calls for a response not unlike the highly successful Ryan White Care Act, a multi-pronged public health approach to the AIDS epidemic.²³

II. Strategies

The ASPPH Task Force recommends adopting several overarching strategies to guide the development of public health initiatives to end the opioid epidemic and prevent it from recurring.

First and most important is the recognition that the array of health and social problems referred to as the opioid crisis has largely been driven by the increased prevalence of opioid use disorder, **a chronic, relapsing brain disease**. Effective prevention and treatment of OUD begins with recognizing that it is caused by repeated exposure to opioids. “The understanding of opioid use disorder as a medical illness is still overshadowed by its misconception as a moral weakness or a willful choice,” write Yngvild Olsen, MD, MPH, and Joshua M. Sharfstein, MD, in a *JAMA* Viewpoint essay on the importance of stigma reduction.²⁴

All stakeholders, the broader public as well as healthcare professionals, must be educated about the drivers, facilitators, and outcomes of OUD. Opioid litigation funds should be designated for a broad social marketing **campaign designed to inform the public and prescribers about opioid risks, reduce stigma around opioid use disorder, and improve access to treatment**, including medications for opioid use disorder (MOUD). Funding for the campaign should include resources for ongoing and rigorous evaluation of its effectiveness and continuous improvement. Funds should be allocated to create and support long-term, sustainable prevention programming at a scale much greater than that which was dedicated for tobacco-use prevention in the tobacco master settlement of 1998.

The opioid crisis is a public health issue that touches all levels of society. It is critical to reach across sectors and engage all possible resources to address the epidemic and reduce associated harms.

Hence, stakeholders operating on the front lines of the crisis, such as public safety, criminal justice, police, corrections, courts, military, and emergency services, must be educated and trained about OUD as a disease. Rhode Island has successfully reduced opioid overdose deaths among individuals leaving prison by permitting access to MOUD during incarceration and ensuring its continuation upon discharge.²⁵ To enhance uptake of this practice, the Substance Abuse and Mental Health Services Administration (SAMHSA) has provided guidance on evidence-based practices for MOUD in jails and prisons.²⁶ **Master settlement funds awarded to states should be mandated to create and scale up access to medications for OUD throughout the criminal justice system.**

Moving away from stigma and moral judgments also could help facilitate the deployment of **evidence-based harm reduction programs** such as broad naloxone distribution, syringe service programs, and supervised consumption facilities (also known as safer injection sites). Funds should be mandated for the implementation, scaling, assessment, and evaluation of these programs.

Health-professions and health-systems education must be strengthened to better inform the healthcare community about the risk and benefits of opioid use. A multi-faceted opioid marketing campaign, disguised as education, resulted in a dramatic increase in opioid prescribing.²⁷ One aspect of the campaign included a mandate from the Joint Commission (which accredits and certifies over 22,000 health care organizations and

programs in the United States), that healthcare organizations assess pain as if it were another vital sign. The introduction and spread of the “Pain Is the Fifth Vital Sign” campaign, and inclusion of pain metrics in the Hospital Consumer Assessment of Healthcare Providers and Systems scores, created incentives for aggressive opioid prescribing. Funding should be used to better educate the medical community about opioid use and to explicitly correct past misinformation. These cautionary notes are not intended to obstruct access to opioids for those with end-stage illnesses or unique circumstances that warrant opioid use for pain. It is, however, noteworthy that studies have suggested that alternative, non-addictive pain regimens can be as effective in many circumstances.²⁸

The likelihood of recovery through **expanded access to medications for opioid use disorder** without judgment or undue penalties or barriers can be increased. Barriers to medications for OUD must be dismantled. Access to such medications on demand²⁹ should be assured in every county in the United States, and payers — private and public — should be required to cover the costs. Recently 39 state attorneys general called on states to remove barriers to access for MOUD.³⁰ Preliminary research shows the feasibility, demand for, and initial positive outcomes of rapid access buprenorphine programs co-located with a syringe services program.³¹

Further, we must discover **new approaches to prevent OUD** through research in a variety of settings, including healthcare, schools, and other community institutions. Funds should be directed to establishing an independent foundation to oversee and administer block grants to support the implementation and rigorous study of initiatives to reduce opioid and other substance misuse in the United States.

It is crucial that we **improve our understanding of the long-term and intergenerational effects of opioid use disorder** on persons, families, health systems, service agencies, communities, and the nation. We should reorganize federal, state, and/or settlement resources for maximum benefit to those stakeholders and harmonize resources into a dedicated stream that holistically addresses the long-term needs of people with OUD.

Recommended strategies include **regulatory reforms** which, although not within the purview of a master settlement agreement, will be incorporated into the ASPPH advocacy agenda. We urge that, consistent with CDC guidelines, opioid pain relievers be treated as highly addictive, controlled substances not typically indicated for long-term use for chronic pain outside of active cancer treatment, palliative care, and end-of-life care; and for which lobbying and marketing are inappropriate. An assessment of direct-to-physician opioid marketing at the county level revealed a significant positive association with elevated opioid mortality one year later.⁵ Along with revisions in opioid drug labeling to discourage long-term use, federal regulations must be changed to **prohibit (or strictly limit) the marketing of opioids to physicians and health systems and to law enforcement and justice systems**. The marketing of naltrexone, a long-acting opioid antagonist medication that blocks the effects of opioids, to corrections and law enforcement systems should also be prohibited (or strictly limited), as the evidence for retention in naltrexone treatment has not yet been demonstrated to be equal in scale and quality to that of other forms of MOUD, such as buprenorphine and methadone.

The Task Force also supports a legislative response to the opioid epidemic using the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act as a model.³² The current state of the opioid problem warrants a similar **comprehensive, multi-part federal effort that combines primary medical care, essential support services, outreach to persons who misuse substances, patient engagement, and access to medications for OUD**.

III. Evidence and Epidemiology

To perform the vital role of preventing, identifying, and treating opioid use disorder, it is critical that the public health community and its partners be equipped with the necessary data and information to understand the size, scope, and location of need. “Epidemiological and clinical data provide context for understanding the range of adverse outcomes directly related to fatal opioid overdose, opioid use and misuse, and opioid use disorder; the medical and social consequences that are driven by opioid misuse; and programs and policies that may either contribute to or to mitigate negative outcomes,” Saloner et al note in their November 14, 2018 article in *Public Health Reports*, “A Public Health Strategy for the Opioid Crisis.”³³

Evidence

Accurate nationwide datasets that can shed light on the multiple dimensions of this complex epidemic are elusive. “Some data systems that were once used by government agencies to gather information on users, consumption, and illegal markets have disappeared over the past several years,” according to a blog post on FiveThirtyEight.³⁴ The author continues, “Other sources that are still available are becoming more difficult to access or don’t provide a clear picture of the problem.”³⁴ For example, the Arrestee Drug Abuse Monitoring system (ADAM), which collected and validated drug use information on male arrestees, was eliminated in 2013, just as opioid overdose deaths hit an all-time high. DAWN, the Drug Abuse Warning Network, operated by the Substance Abuse and Mental Health Services Administration (SAMHSA), was discontinued in 2011 but is being reinstated in 2019.

When lives are lost, differences among state policies and systems in the ascertainment of causes of death add to the data challenge. “Lack of standardization in toxicology and coding practices among medical examiners and coroners can lead to misclassification of cause of death, poor identification of types of opioids involved in overdoses, and undercounting of intentional poisonings. Additionally, focusing on mortality does not adequately disentangle fatality risk per user (or per use) over time and specific drugs involved in overdoses—research questions that could be informed by nonfatal overdose surveillance data or drug seizure data,” Saloner and colleagues observe.³³

To generate valuable, actionable data and information, we must **implement improved metrics on all dimensions of the epidemic**, including surveillance of the incidence and prevalence of opioid use disorder, injection drug use (IDU), fatal and nonfatal overdoses, access to treatment, and the social and health consequences of opioid use. The field is further hindered by a lack of common definitions of the disease and treatment effectiveness that account for the complexity of treatment type, dose, and duration. New tools and methods are required, as well as the interoperability of state electronic death registration systems and enhanced internet- and hospital-based surveillance. There are successful examples. Rhode Island³⁵ and New Jersey³⁶ have developed data sharing initiatives that make the latest data on addiction and overdose available to all.

The CDC National Center for Health Statistics project, “Modernizing the Infrastructure for Capturing Drug Death Data and Enhancing Research on Opioid Poisoning using Death Certificates’ Literal Text Field,” has received pilot funding, but there is much more to be done.³⁷ These efforts can be enhanced by developing updated consensus case definitions for each of the dimensions of the epidemic, as well as the natural history of

substance use disorders, and disseminating those definitions through the public health community.³⁸ These efforts, conducted in parallel, can — if adequately resourced and managed — drive the discovery of tools and approaches that strengthen prevention and resilience and can be used to address the country’s next as-yet-unknown drug abuse problem, obviating the need to keep inventing new surveillance approaches as new drug epidemics emerge.

Technology can provide valuable assistance with the challenges of generating accurate, actionable data. Funds should be used to **create a national open data-sharing center on substance use**. The center’s approach should be based on “FAIR” (findable, accessible, interoperable, and reproducible) data standards that conform with HIPAA and 42 CFR Part 2 to assure patient privacy. We can make efficient use of informatics tools to identify hazardous prescribing and assess addiction risk through electronic health records within the purview of the patient-provider relationship.^{39,40} We can also use computing resources at national labs, universities, and commercial entities for computational modeling⁴¹ to forecast opioid use disorder, potential hotspots for improved primary and secondary prevention activities,⁴² interdiction of imported fentanyl and fentanyl-containing street drugs,⁴³ and treatment access to ensure that resources are wisely and effectively deployed. Further, we can **leverage national computational research resources for sophisticated data science approaches to risk mitigation** that include targeted theory-based messaging for primary, secondary, and tertiary prevention strategies.

Epidemiology

Public health has a unique role as a neutral convener on evidence-based practices, but more knowledge is needed about the epidemiology of substance use. “Although robust epidemiological studies have been performed for small geographic areas, nationally representative longitudinal studies of people who use opioids are lacking, making it difficult to examine initiation of use and transition across various misused substances,” write Saloner et al.³³ Greater study and analysis of the distribution and determinants of opioid use disorder, including social and corporate determinants, are needed to guide policy decisions and evidence-based practice. We must **standardize, use, and expand rigorous observational epidemiological surveillance tools** to inform and continually evaluate population-level interventions.

The recently created Population Assessment of Tobacco and Health (PATH) study following a large panel of tobacco users and non-users is one model approach.

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IV. Anti-Stigma and Harm Reduction Efforts

Stigma is defined as “a mark of disgrace or infamy; a stain or reproach, as on one’s reputation.” Opioid use disorder is often regarded in this way, and its victims blamed and judged. Yet OUD is a chronic, relapsing brain disorder — a medical illness — and should be treated as any other physiological condition.

“Addiction is a chronic disease of brain reward, motivation, memory, and related circuitry,” according to the American Society of Addiction Medicine.⁴⁴ “Much like type-2 diabetes, hypertension, and asthma, opioid addiction cannot be cured; however, it can be effectively treated and managed.”⁴⁴

A systematic review of studies of opioids for chronic pain found that fully 22-30 percent of patients that receive opioid for chronic pain misuse them, and 8-12 percent develop an addiction.⁴⁵ There are effective medications to support long-term recovery for those with OUD,⁴⁶ and the fact that stigma is still so pervasive is a failure to respond compassionately to an epidemic that has raged for more than two decades.²

Despite the efforts of the healthcare community, stigma surrounding OUD persists. A 2014 Johns Hopkins Bloomberg School of Public Health study found that people are “significantly more likely to have negative attitudes toward those dealing with drug addiction than those with mental illness.”⁴⁷ Four years later, in a spring 2018 survey conducted by the Associated Press and the NORC Center for Public Affairs Research at the University of Chicago, 44 percent of respondents said OUD indicates a lack of willpower, and 32 percent said it is caused by a character defect or bad parenting.⁴⁸

These beliefs, especially when demonstrated in professions that interact closely with persons suffering from OUD, such as corrections, law enforcement, and the judiciary, as well as when shared by policy makers and legislators, present significant barriers to effective prevention, treatment, and harm reduction efforts.

Stigma also exists within the healthcare community. Studies of physician and pharmacist attitudes and behaviors toward patients with OUD, including those engaged in MOUD, are emerging and troubling. Recent studies have found significant biases relating to MOUD patients among both physicians and pharmacists⁴⁹ and little communication between the professions to clear up misconceptions about prescribing or dispensing MOUD prescriptions.⁵⁰

“The more shame associated with drug addiction, the less likely we as a community will be in a position to change attitudes and get people the help they need,” said Beth McGinty, PhD, an associate professor in the Department of Health Policy and Management at the Johns Hopkins University Bloomberg School of Public Health. “If you can educate the public that these are treatable conditions, we will see higher levels of support for policy changes that benefit people with mental illness and drug addiction.”

Stigma also can present a barrier to treatment for affected individuals. “Stigmas run deep when it comes to addiction. Whether it is the person in recovery constantly being asked why she doesn’t drink or the person who is addicted to opioids but isn’t ready to seek help because he couldn’t possibly be a ‘drug addict,’” Jenny

Mincin, PhD, MPhil, MPA, wrote in “Addiction and Stigmas: Overcoming Labels, Empowering People,” a chapter in *New Directions in Treatment, Education, and Outreach for Mental Health and Addiction*.⁵¹ The ASPPH Task Force believes that **funds should be devoted to anti-stigma and harm reduction efforts** including:

- A national anti-stigma campaign around opioid use disorder and its treatment;
- Anti-stigma training programs for all professionals likely to come into contact with persons with opioid use disorder and those seeking treatment for it;
- Reducing barriers to prescribing medications for opioid use disorder and ensuring that they are widely available; and
- Systematically elevating the voices and telling the stories of people who use drugs and those in recovery, including those with and without public profiles.

Anti-stigma information and education

The Task Force recommends the use of funds to mount a **large-scale national OUD anti-stigma campaign**, and urges that sufficient funding be set aside for this effort. The campaign should be adapted for multiple stakeholders from the general public to specific professions, as well as regional and cultural sensitivity and relevance; based in scientific principles of communication science; and rigorously evaluated. Getting this message across is crucial to response and recovery. Massachusetts’ “State Without StigMA” campaign⁵² and New York’s “ThriveNYC” initiative⁵³ are useful models.

The Task Force recommends the use of funds to mount a large-scale national OUD anti-stigma campaign, and urges that sufficient funding be set aside for this effort.

Second, the Task Force urges the development and implementation of training programs for healthcare, public safety, criminal justice, police, corrections, courts, military, and emergency services personnel on addiction as a chronic relapsing brain disease and available evidence-based treatment. In its own task force report on the opioid epidemic, the American Medical Association cites as a factor contributing to stigma “the criminal justice system’s unwillingness to yield to medical judgment in the treatment of opioid-use disorders.”⁵⁴ While there is some progress in this area,²⁶ to make significant gains for those interfacing with the criminal justice system, change could be greatly facilitated by focused training with this large group of key stakeholders.

Similarly, judicial system employees should be mandated to undergo evidence-based addiction training. In its report, “Ten Standards of Care: Policing and the Opioid Crisis,” the Police Executive Research Forum urges the law enforcement community to promote education on addiction and stigma within its ranks as well as within its communities.⁵⁵ Medication-assisted treatment continues to be controversial in this sector, though persons seeking MOUD, even if involved in probation or on parole, are protected under the Americans with Disabilities Act.⁵⁶ Stigma and barriers to MOUD with justice-system involved patients is particularly problematic because incarcerated patients have a higher risk of overdose and overdose fatality, especially immediately after release. Massachusetts public health researchers have estimated that people leaving jail or prison are 120 times more likely to die of an opioid overdose than the rest of the adult population.⁵⁷

Decreasing the stigma with which law enforcement and corrections personnel view OUD can help pave the way for incarcerated people to access treatment. Currently and formerly incarcerated individuals should be viewed as patients with a medical condition. Patients have a right to MOUD, according to legal experts.⁵⁸

Promoting Recovery

We should **elevate the voices of those in recovery**, including those with and without public profiles. Through a national campaign, a public face can be put on opioid use disorder and help decrease stigma. For example, Faces & Voices of Recovery,⁵⁹ a national advocacy organization, highlights the stories of people recovering from addiction on its website and social media platforms, and the organization also offers an open data-sharing resource known as the Recovery Data Platform (RDP).⁶⁰ The RDP tells stories through data and offers organizations and service providers access to the analytics and metrics of recovery. SAMHSA offers a digital storytelling guide and webinars for creating personal videos about recovery.⁶¹

Peer Specialists

The ASPPH Task Force views well-trained peer support specialists and navigators as key resources in helping to abate the opioid epidemic. “MAT [medication assisted treatment] is much more effective with ongoing services and supports, and peer recovery coaches can provide this support and help people link to services,” write Gagne et al in a June 2018 overview of peer workers in the behavioral health workforce.⁶² “MAT has become a critically important service in the wake of the opioid epidemic in the U.S., and peer recovery coaches are assisting people using MAT to adhere to treatment and to regain valued roles in the community.”⁶² To enhance the effectiveness of peer support specialists and navigators, the Task Force recommends careful alignment of such assets in the community and a robust implementation framework for peer programs.

There is ample precedent for state and federal funding for peer providers, but most currently funded services are for mental health; only a third of states have similar Medicaid provisions for substance use disorder support.⁶³ The ASPPH Task Force believes that **funds should be devoted to training programs** that include:

- Deploying learning and implementation models for peer support specialists and navigators applicable to both urban and rural settings, and developing the evidence of their efficacy;
- Mandating that state-certified peer support activities are reimbursable by insurance at a market rate commensurate with the value gained by these cost-effective supports; and
- Delivering targeted educational programs for professionals most likely to interact with and serve people with OUD.

Harm Reduction

Harm reduction principles and programs are stigmatized in many areas of the United States; some forms of harm reduction are even illegal in some states. Harm reduction is an approach that focuses on reducing the negative consequences and risky behaviors linked to substance use. It emphasizes trust, respect, and a nonjudgmental stance; and it assumes that clients want to make positive, incremental changes. “By incorporating strategies on a continuum from safer drug use to managed substance use and up to abstinence,

harm reduction practice helps clients affect positive changes in their lives,” according to a fact sheet from the National Health Care for the Homeless Council.⁶⁴ The organization lays out these principles for harm reduction:

- Individual’s decision to use is accepted;
- Individual is treated with dignity;
- Individual is expected to take responsibility for his or her own behavior;
- Individuals have a voice;
- Focus on reducing harm, not consumption; and
- No pre-defined outcomes.

To disseminate the successes of harm reduction programs, the ASPPH Task Force urges the **creation and promotion of a robust national information exchange on harm reduction and evidence-based harm reduction programming**. Known effective harm reduction programs include:

- Overdose education and naloxone distribution programs;
- Syringe services programs (SSP);
- Supervised injection facilities or safer injection facilities (SIF);
- Low-threshold or emergency access to buprenorphine²⁹ to facilitate initiation into treatment and enhance retention; and
- Testing for fentanyl and fentanyl analogs with test strips.

Naloxone is an opioid antagonist that can reduce the incidence of death in the event of an opioid disorder. Its use is promoted by so-called “Good Samaritan” laws that have been enacted in 46 states and the District of Columbia. In every state but Nebraska, pharmacists are permitted to dispense naloxone without a prescription, according to the Prescription Drug Abuse Policy System.⁶⁵ In a Public Health Advisory issued in April 2018, U.S. Surgeon General Jerome Adams, MD, MPH, describes naloxone as a “potentially life-saving medication,” reviews the available forms, and encourages healthcare providers to “[p]rescribe or dispense naloxone to individuals who are at an increased risk for opioid overdose and to their friends and family.”⁶⁶ A poll of 3,000 households conducted by National Public Radio in May 2018 revealed that most Americans know about naloxone and would be willing to use it.⁶⁷ Naloxone’s effectiveness is likely to be substantially improved if combined with other supportive interventions such as referral to treatment. Brief education is adequate when distributing naloxone.^{68,69}

Syringe services programs (SSPs) are community-based public health programs that provide sterile injection equipment, safe disposal of used syringes, and testing for HIV and hepatitis. SSPs have clear benefits: increased entry into treatment of persons who use program services, reduced needle-stick injuries, reduced rates of HIV and hepatitis C among program participants, and lower costs attributable to reduced infection.⁷⁰ Many SSPs also test for hepatitis A & B and some even provide vaccinations and primary care.

The ASPPH Task Force asserts that creating and expanding syringe services programs, including the purchase of sterile syringes with federal dollars, is an appropriate use of funds and that their benefits are so compelling that states should be required to establish syringe services programs as a condition of receiving federal funds to combat the opioid epidemic. Currently, such programs exist in 39 states, Puerto Rico, and the District of

Columbia, according to the Kaiser Family Foundation.^{71,72} The ASPPH Task Force urges the federal government to discontinue its ban on using federal funds for the purchase of sterile syringes.

Supervised injection facilities (SIFs), or safer injection sites, offer many of the same benefits as SSPs but are more controversial. According to the nonprofit Harm Reduction Coalition (HRC):

*SIFs are sanctioned and supervised spaces for the hygienic consumption of pre-obtained drugs in a non-judgmental environment and under the observation of trained staff. SIFs represent a public health intervention operating as part of a wider network of services for people who use drugs, woven into local networks of coordinated strategies to address the individual risks and community impact of drug use. These programs aim to reach underserved and marginalized populations, address health inequities, and resolve public health and safety tensions related to public injecting.*⁷³

In a 2016 blog post about SIFs, HRC Policy Director Daniel Raymond summarizes key lessons for American policymakers. He states:

- *People who use SIFs take better care of themselves, reduce or eliminate needle sharing, use drugs more safely, and ultimately reduce their drug use.*
- *SIF participants gain access to other medical and social services and entry into drug treatment.*
- *There has not been a single overdose death in any of these programs over many years of operation and many thousands of supervised injections.*
- *SIFs do not increase drug use in the area, nor do they encourage young people to initiate drug use.*
- *Crime and public nuisance decrease in the areas around these programs.*⁷²

Although more than 100 SIFs exist in countries around the world, there currently are no legally sanctioned facilities in the United States. Communities are actively engaged in attempting to establish these sites.⁷⁴ NPR reports that at least a dozen cities are attempting to start official sites.⁷⁵ A recent poll of Philadelphia residents in a community discussing the possibility of a safe injection site within its boundary indicated that a majority of both individual respondents and businesses supported the facility.⁷⁶

A 2014 literature review published in the journal *Drug and Alcohol Dependence* concluded that “supervised injection services fulfilled their harm reduction objectives” and did not increase drug use or crime.⁷⁷ A detailed review of evidence by researchers at Thomas Jefferson University came to a similar conclusion.⁷⁸ A cost benefit analysis of a potential safer consumption site in Seattle found that it “save[d] lives and result in considerable health benefits and cost savings.”⁷⁹

In a letter to the *New York Times* on August 31, 2018, ASPPH Board Chair Donna J. Petersen, MHS, ScD, CPH, described safer injection sites as a “proven harm reduction strategy” and “an option that benefits both patients with substance abuse disorder and communities.”⁸⁰ She concluded the letter with a call to policymakers and law enforcement to “ensure that states and localities that are struggling to deal with the consequences of our national opioid epidemic are able to put in place proven and innovative public health measures that reduce the harm being caused to individuals and communities.”⁸⁰

“We call on policymakers and law enforcement to ensure that states and localities that are struggling to deal with the consequences of our national opioid epidemic are able to put in place proven and innovative public health measures that reduce the harm being caused to individuals and communities.”

-- Donna J. Petersen, MHS, ScD, CPH

As one of many promising public health initiatives to address the opioid crisis, the ASPPH Task Force urges the federal government to discontinue its threat to criminalize the establishment of these sites.

Detection of fentanyl and fentanyl analogs is crucial to public safety. These substances were associated with more than half of the overdoses in 10 states during the second half of 2016, according to the Center for Disease Control and Prevention (CDC).⁸¹ Many people who suffer from OUD are unaware that the drugs they are using are laced with fentanyl or its analogs. Funds should be used to make fentanyl detection and interdiction programs more robust and to develop a sanction strategy. Studies such as FORECAST (Fentanyl Overdose Reduction Checking Analysis Study), which was funded by the Bloomberg American Health Initiative, have tested emerging technologies to identify fentanyl in illicit drugs;⁸² their scope and area of inquiry should be expanded. The resulting technologies, used for “drug checking” that allows people to protect themselves, can help guide them to other services and save lives.

The FORECAST study found that “fentanyl testing strips had the lowest detection limit and the highest sensitivity and specificity for fentanyl of the technologies assessed.”⁸² A small group study in Rhode Island showed that the strips could be useful in harm reduction settings and could lead to increased engagement in behaviors to prevent overdose.⁸³ In another study, 81 percent of the test population used the test strips provided, and persons with a positive result for fentanyl were five times more likely to report changes in drug use behavior.⁸⁴ Naloxone promotion programs are effective and should be supported, but naloxone is not always available. Hence, research should be conducted on additional strategies for self-protection by users, such as “slow-shots,” “tester shots,” and sampling of drugs at time of purchase, and the user community should be informed about such strategies if shown to be effective. The ASPPH Task Force believes that **funds should be devoted to harm reduction efforts** including:

- Create and promote a robust national information exchange on harm reduction and evidence-based harm reduction programming;
- Scale up syringe exchange programs and make syringe service programs a requirement for states to receive MSA funds;
- Establish legal supervised injection facilities in areas of high need, prior to the emergence of outbreaks of infectious diseases such as hepatitis B and C and HIV;
- Enhance harm reduction programs to help people who use drugs detect fentanyl and related analogs;
- Expand public messaging about evidence-based harm reduction programming;
- Further expand and support naloxone distribution efforts; and
- Fund a robust research and evaluation program that focuses both on effectiveness and the impact of harm reduction interventions on individuals and communities.

V. Primary Prevention

Primary prevention strategies for preventing opioid misuse and opioid use disorder are critical to stopping the epidemic. Primary prevention programs should reduce exposure to highly addictive drugs, help individuals remain resilient even when exposure occurs, and produce an environment that reduces the threat of exposure.⁸⁵ The ASPPH Task Force recommends that a significant portion of funds be directed at primary prevention efforts. These efforts should be variously targeted toward the public, healthcare providers, and law enforcement professionals.

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The Task Force recommends that if a master settlement agreement is agreed upon, that significant funds should be used to **establish and support an independent entity to develop targeted programs and initiatives to increase public awareness of the risks of opioid misuse and opioid use disorder and to promote primary prevention at the population level**. Many states have successfully created community infrastructure to support these efforts, including networks of local coalitions with diverse stakeholders. The national truth[®] youth smoking prevention campaign, initiated in 2000 by the American Legacy Foundation – now the Truth Initiative[®] (with funding from the tobacco MSA), had a substantial impact on changing youth and young adult attitudes about smoking,¹⁶ reducing youth initiation of smoking,¹⁵ accelerated the decline in youth smoking prevalence¹⁴ and was cost-efficient.¹⁷ Simultaneously, it is important to address the primary drivers of OUD and to develop alternatives; for example, to educate consumers and patients on alternatives to opioids for pain relief.

It is critical to fund the nation's mental health infrastructure to ensure access for the population that is self-medicating or at risk for self-medication. In particular, prevention programming should include training on adverse childhood experiences⁸⁵ and be based on trauma-informed care, which attends to such experiences in a person's life.⁸⁶ Increases in adverse childhood experiences are associated with graded increases in affective, other cognitive, physical, sexual, and substance abuse problems later in life.⁸⁷ Hence, aligning prevention with trauma-informed care is essential.

Appropriate opioid use is an important part of patient education efforts. Many hospitals and health systems have instituted written agreements in which patients receiving prescriptions for opioid pain relievers must acknowledge awareness of the risks of addiction and overdose. Many state medical societies stipulate informed consent in their prescribing guidelines.⁸⁸

Primary prevention must take a wide lens

In Olsen and Sharfstein’s “The Opioid Epidemic: What Everyone Needs to Know”,⁸⁵ the authors state that a “wide lens” approach is called for with respect to prevention programs for addiction. This is because the most effective programs call for skill development for youth prior to exposure to drug threats. Programs that have been proven effective over many years include youth and community development approaches such as PROSPER⁹⁰ and Communities that Care.⁹¹ Both programs are aimed at youth skill acquisition for protection against multiple health threats. There are numerous resources to support communities looking for evidence-based prevention approaches that can be tailored for their specific setting and need. One of the best places to start looking for such programs is at the Substance Abuse and Mental Health Services Administration’s *Evidence-Based Practices Resource Center*.⁹²

Educating public health specialists

Throughout the country, many of the leaders currently responding to the opioid crisis have had the benefits of formal training in the key disciplines of public health, including epidemiology, biostatistics and data science, and behavioral and community health. The Task Force recommends that funds should be used to **support formal public health training programs at schools and programs of public health focused on OUD**.

Educating healthcare providers

Despite recent decreases in opioid prescribing, the United States continues to prescribe far more opioids per capita than other developed countries.⁸⁹ Primary prevention of OUD requires more cautious opioid prescribing. Although the CDC has issued independent prescribing guidelines²⁸ and the FDA requires opioid manufactures to sponsor continuing education courses,⁹⁰ more training is needed, as are improved, evidence-based learning resources.

The Task Force recommends that funds be used to **create and implement expanded, credible prescriber and dispenser training by one or more independent organizations**, without influence from pharmaceutical companies, to improve prescribing practices. Further, it should address stigma related to both prescribing and dispensing MOUD therapeutics by all health professionals, including prescribers, dispensers, and non-prescribing direct-care professionals such as nurses, counselors, social workers, hospital administrators, and others with whom patients interact.

Academic detailing has been shown to be effective in educating physicians and other healthcare providers about safe prescribing practices for opioids and improving those prescribing practices.⁹¹ Similarly, a qualitative evaluation of academic detailing interventions at seven Veterans Administration health systems found that academic detailers play a key role in motivating providers’ behavior change.⁹² The Task Force recommends that funds be used to underwrite **extensive academic detailing and counter-detailing on opioids** to correct the inaccurate and misleading claims previously made by the companies that manufacture those drugs, messages that continue to confuse or mislead some patients and prescribers.

Engaging and supporting law enforcement

Funds should be used to **create and implement collaborative models with law enforcement**, such as RxStat in New York,⁹³ that bring public health and law enforcement together around data-driven approaches to understand the patterns and characteristics of opioid use disorder and to formulate targeted interventions that recognize substance use disorder as a treatable medical condition with multiple physical, behavioral, and environmental drivers. A cross-sector partnership facilitated by a grant from Bloomberg Philanthropies that includes the CDC Foundation and Johns Hopkins University is piloting a similar program in up to 10 states.⁹⁴

Bring public health and law enforcement together around data-driven approaches to understand the patterns and characteristics of opioid use disorder and to formulate targeted interventions that recognize substance use disorder as a treatable medical condition with multiple physical, behavioral, and environmental drivers.

Funds should also be used to develop and implement evidence-based law enforcement policies, including police practices directed at drug users. The tide is turning toward treating drug use as a public health issue — rather than a criminal activity — and toward providing assistance and support to people who use drugs rather than incarcerating them. In a leading example, law enforcement professionals in the city of Seattle have decided to stop charging people for possessing small amounts of drugs and instead attempt to divert them into treatment.^{95,96} Given that OUD is a medical condition for which public safety agencies provide substantial interventions, law enforcement should assist health care, harm reduction, and public health professionals by supporting their interventions, rather than attempting to lead interventions.

Drug disposal as a primary prevention strategy

Ending the careless storage and disposal of unused opioids from homes is imperative and proven as a strategy to prevent the misuse of prescribed drugs. Simple promotion of such events with inexpensive advertising has been shown to increase the total amounts of prescribed drugs being taken to disposal sites,⁹⁷ yet many such disposal receptacles are within police departments, which could be seen as intimidating or inconvenient for the general public to access. Additional and more diverse disposal sites should be funded.

VI. Access to Medications for Opioid Use Disorder

Improved access is urgently needed for all medications used to treat opioid use disorder, including methadone, buprenorphine, and naltrexone. Researchers estimate that ready access to buprenorphine could reduce opioid overdose deaths by as many as 30,000 per year.⁹⁸ In France, enhanced access sharply curtailed the epidemic, resulting in a fivefold reduction in heroin-related deaths.⁹⁹ Yet many barriers confront patients who seek access to medication-assisted treatment for OUD, including a lack of available prescribers, initial authorization and reauthorization requirements for insurance reimbursement, and “fail first” criteria wherein other forms of treatment — typically, abstinence — are suggested before MOUD.^{46,100} SAMHSA estimates that only one in three patients with opioid addiction receives treatment with medications.¹⁰¹ There have been several recent calls for increased physician training in MOUD, eliminating the waiver mandated by the Drug Addiction Treatment Act of 2000 (DATA 2000) (the “X waiver”), integrating OUD care into mainstream healthcare, and dismantling other barriers that restrict patients’ access to MOUD.^{98,102,103}

As of January 2019, almost a third of Americans were living in a county without a buprenorphine provider.¹⁰⁴ Despite increases, only 7 percent of practitioners have obtained the necessary DATA 2000 waiver to prescribe buprenorphine.¹⁰⁵

The ASPPH Task Force believes that funds should **facilitate local access to MOUD**. This access should be ensured in every county in the United States and can be facilitated by deregulating buprenorphine prescribing, maximizing the use of telemedicine, and suspending the need for X waivers. Changes in the regulatory environment have been recently urged by state attorneys general.

The ASPPH Task Force believes that funds should facilitate local access to MOUD. This access should be ensured in every county in the United States and can be facilitated by deregulating buprenorphine prescribing, maximizing the use of telemedicine, and suspending the need for X waivers.

Telemedicine can be an important tool in treating people with addiction and substance use issues.¹⁰⁶ Healthcare providers can use connected-care video communication platforms to deliver MOUD to people struggling with OUD through a combination of behavioral health therapy and prescription drugs. Care can be managed virtually, giving vital access to patients in remote and rural locations, as well as places where there may be a shortage of X-waivered providers.^{106,107}

Pharmacists also can be more effective in the identification and treatment of people struggling with opioid use disorder. In one successful Boston example, emergency room pharmacists connected patients with MOUD providers and critical treatment services.¹⁰⁸ Funds should be used to extend training to pharmacists to provide these valuable services. Further, there is a growing body of research on the expansion of MOUD introduction and access for any patient who needs it in emergency room settings,^{109,110} which has also been shown to be cost effective.¹¹¹ Such access should be facilitated nationwide.

Aligning public and private insurers around the need to optimize access to MOUD can help dismantle some of the most pervasive barriers. **Payers should reimburse providers for MOUD equitably across all states.** In Pennsylvania, the state reached an agreement with commercial insurers to align prior-authorization processes for opioid prescriptions.¹¹² This model should be replicated nationwide. Private payers should be required to: revise policies and procedures that block their insured patients from diagnosis and treatment, including pre-authorization; provide equitable treatment on demand; and eliminate any provision that compels patients to pay for methadone and/or buprenorphine.

Funds also should be used to encourage and leverage partnerships among prevention specialists, treatment providers, corrections personnel, and law enforcement to ensure continuity of care for opioid use disorder upon discharge from jail, prison, or drug court. Rates of opioid use in the criminal justice system are much higher than in the general population,¹¹³ with estimates of opioid use disorder in up to 35 percent of prisoners.¹¹⁴ Once discharged, former inmates have a 75 percent increased risk of relapse and overdose, and are 40 times more likely to die of an opioid overdose, according to SAMHSA estimates.²⁶ Continuation of MOUD after release has been shown to decrease the risk of overdose and improve the likelihood of continued treatment.¹¹⁵ Community-based treatment can improve behavioral and physical health, promote social well-being, and prevent or reduce the likelihood of contact with the criminal justice system.¹¹⁶

VII. Research

Aligned with recommendations from National Institutes of Health Director Francis Collins, MD, PhD, and National Institute on Drug Abuse Director Nora Volkow, MD,¹¹⁷ the ASPPH Task Force recommends that a significant portion of funds be devoted to research activities that could play a key role in understanding the biological and other roots of addiction, more effective ways to treat addiction and overdose, and nonaddictive alternatives to opioids for the treatment of chronic pain.

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In particular, the Task Force recommends funding research in these key areas:

Understanding of the causes and remedies for the psycho-social drivers of the substance use epidemic

The U.S. drug overdose epidemic grew exponentially for decades. During this time, there have been changes in the predominant drugs, changes in law enforcement and other policies, and changes in the demographic characteristics of the populations most severely affected, yet the epidemic continued to grow.² Drug overdose deaths have been shown to be associated with less education, increased economic challenges and stress,¹¹⁸ but how these factors arise and spread within a society, and how the affected populations then serve as a substrate for the growing drug use epidemic, is not well understood. While it is possible that the current opioid epidemic may be controlled without addressing these issues, it is highly likely that it will be necessary to address these root social determinants of the ongoing substance use problem. Otherwise, we are unlikely to make sustained and lasting progress against the drug epidemic when the current opioid crisis is supplanted by the next wave of substance abuse.

Primary prevention programming

Though there is evidence for effectiveness of some primary prevention approaches for substance use disorder, there is little known about how effective such programs are in comparison with one another, the amount of intervention needed for lasting change in multiple contexts, and sustainment mechanisms for prevention programming.

Dissemination and implementation studies to expand collaborations between health and law

There are many promising approaches, but as an example, the New York RxStat initiative, begun in 2011, has proven to be a successful model of collaboration between public health and public safety to reduce overdose deaths. Technical assistance is freely and widely shared, and the model should be implemented in the U.S. communities hit hardest by the opioid epidemic.⁹³

Studies related to expanding access to medication-assisted treatment, as well as other forms of treatment for OUD

As previously discussed, the potential impact of expanded access to medication-assisted treatment is great;⁴⁶ however, critical questions remain. In order to maximize that potential, the Task Force recommends funding research on:

- The effectiveness of heroin-assisted or hydromorphone-assisted treatment¹¹⁹ and other options beyond the currently available MOUD therapeutics for those persons who do not respond to buprenorphine and methadone;¹²⁰
- The costs and long-term benefits of treatment with naltrexone in comparison with other forms of MOUD;¹²¹
- Vaccines that may block the effects of opioids;¹²²
- Long-term injectable medications that assist with opioid treatment;¹²³⁻¹²⁵ and
- Alternatives to opioids for long-term chronic pain relief.¹²⁶

Funds should be dedicated to research into developing effective, addiction-free pain relievers and other interventions to address the needs of those in distress.

Computational modeling and simulation

The dynamics underlying the drug overdose epidemic are complex and evolving. Computational modeling and simulation of the epidemic can be used to analyze historical patterns, simulate possible future scenarios, forecast impacts and resource requirements, and evaluate the likely effectiveness and cost-effectiveness of control policy options.¹²⁷ New mechanisms for data acquisition and sharing, big data analytics, modeling of drug use behavior, and optimization of resource allocations could be powerful tools in combating the epidemic.

Biology and sociology

Further investigation into the biology and the sociology of opioid use disorder is also needed, including predicting how people will respond to certain treatments and how to individualize treatment with regard to medication levels and psychosocial supports.¹²⁸ Finally, the study of clinical decision support tools will better equip healthcare providers to treat these patients and to integrate treatment into mainstream healthcare.

VIII. Evaluation and Implementation Science

Prevention, treatment, education, and other harm mitigation initiatives resulting from a potential master settlement agreement will require evaluation, both to demonstrate the effectiveness of the investments and to substantiate their benefits to people and society. The strategies outlined in this report will be undertaken by many different organizations and entities and should be done in a way to facilitate coordination, adherence to best practices in various disciplines and fields, and with maximum benefit to affected and potentially affected populations. The model used by the State of New York to evaluate its Ryan White Care programs might be a model approach if nationally scaled.¹²⁹

It is useful to consider the many different interventions proposed herein as existing along the continuum of substance use disorder treatment.¹³⁰ We propose evidence-based strategies that have been proven to work for primary prevention, early intervention, engagement with treatment services, treatment access and retention, and harm reduction. At each point along the continuum, there are many different stakeholder groups and systems with which different program activities will engage; each will seek to maximize programmatic reach into those stakeholder groups, including the population at large with regard to primary prevention and stigma reduction. A robust literature has emerged in the past two decades concerning the extent to which systems and individuals adopt and adhere to these evidence-based practices (EBP). The field, known as Dissemination and Implementation (D&I) science, is aimed at accelerating and improving the quality of adoption of EBP with high fidelity to their intended approach and purpose. There are excellent D&I models, effective methods, validated evaluation tools, and robust practitioner communities driving this approach.¹³¹ Given the importance of the substance abuse problem to our national health and well-being, evaluation activities should be planned within a dissemination and implementation science framework to maximize impact and return on investment.

No agency, university, or governmental entity is capable of objective evaluation for the many activities listed herein. Hence, should a settlement agreement be reached, a multi-site, multi-institutional collaborative evaluation structure should be established that will leverage the strengths of different universities and agencies toward an effective, coordinated approach. The Task Force proposes a multi-institutional collaborative, with specialty advisory teams to guide specific evaluation activities that would sub-contract to specialized vendors located at universities, federal agencies, and non-governmental organizations. Advisory teams will require, at a minimum, expertise in coordination of multi-site teams, coordination of designated outcome variables and other study data characteristics, dissemination and implementation science, data science, securing community stakeholder input and engagement, field-based pragmatic trials, epidemiology, biostatistics, addiction science, and prevention science. These centers also will serve as the engines to develop new and innovative evaluation methodologies, given the urgent need for rapid evaluation feedback as interventions are brought to scale.

Finally, persons suffering from OUD can be stigmatized, dislocated from family and other supports, have untreated physical and mental comorbidities and many other characteristics that make them a highly vulnerable group. Evaluating interventions, treatment protocols, and study designs for such vulnerable populations will require innovative and sensitive strategies that must evolve as the epidemic runs its course but must also be grounded in the principles of public health that assure dignity, fairness, equality, and compassion as well as elevate human interaction, community, and sense of purpose. Persons affected by OUD must be at the table when such planning takes place and decisions are made. Presently, they are almost never included in such conversations and do not have a voice in decisions that directly affect them.

IX. Regulatory and Legislative Reforms and Voluntary Industry Changes

Congress, the Administration, and various federal and state regulatory agencies have essential roles to play in addressing the opioid crisis. All have taken some important steps to expand treatment access, address prescribing issues that contributed to the crisis, and interdict opioid supplies, both those diverted from lawful distribution outlets and those produced by clandestine laboratories. However, these government entities have paid less attention to addressing the social determinants that make our communities fertile territory for substance use disorder, provided lax federal agency oversight of opioid manufacturers, and ignored unconscionable industry marketing and distribution practices. The opioid manufacturing and distribution industries played key roles in promoting both governmental and non-governmental policies that exacerbated and indeed may have created the crisis. Although those in the opioid business have First Amendment rights to engage in advocacy and marketing, a master settlement agreement would provide a unique opportunity for industry to delineate the limits of its role in national and state opioid policy deliberations going forward. In the Task Force's view, they should voluntarily withdraw from policy advocacy.

Government entities have paid less attention to addressing the social determinants that make our communities fertile territory for substance use disorder, provided lax federal agency oversight of opioid manufacturers, and ignored unconscionable industry marketing and distribution practices.

U.S. Food and Drug Administration

The Task Force recommends that the FDA's review and approval of drug applications for pain medications should be drastically modified to explicitly focus on the balance of risks and benefits to public health. Products to address and manage pain are critically important tools in serving the needs of affected patients. However, outside of active cancer treatment, palliative care, and end-of-life care, the promotion of opioids for long-term use for chronic non-cancer pain is inappropriate and should be prohibited.

In considering the approval of novel opioid products or the removal from the market of existing opioid products, the FDA should adopt the recommendations of the National Academies of Sciences (NAS) regarding the utility of a revised cost-benefit framework.¹³² As noted by the NAS, the investigational drug evaluation process has important limitations with respect to the approval of all drugs in the opioid class. The NAS report notes that "showing that a drug has substantial evidence of efficacy does not necessarily mean that the drug is more effective than currently available therapies, or that the efficacy demonstrated is clinically meaningful."¹³²

The National Academies' recommendation, with which we concur, states:

The U.S. Food and Drug Administration (FDA) should utilize a comprehensive, systems approach for incorporating public health considerations into its current framework for making regulatory decisions regarding opioids. The agency should use this approach, in conjunction with advisory committee input, to evaluate every aspect of its oversight of prescription opioid products in order to ensure that opioids are safely prescribed to patients with legitimate pain needs and that, as actually used, the drugs provide benefits that clearly outweigh their harms. When recommending plans for opioids under investigation; making approval decisions on applications for new opioids, new opioid formulations, or new indications for approved opioids; and monitoring opioids on the U.S. market, the FDA should explicitly consider benefits and risks to individual patients, including pain relief, functional improvement, the impact of off-label use, incident opioid use disorder, respiratory depression, and death; benefits and risks to members of a patient's household, as well as community health and welfare, such as effects on family well-being, crime, and unemployment; effects on the overall market for legal opioids and, to the extent possible, impacts on illicit opioid markets; risks associated with existing and potential levels of diversion of all prescription opioids; risks associated with the transition to illicit opioids (e.g., heroin), including unsafe routes of administration, injection-related harms (e.g., HIV and hepatitis C virus), and OUD; and specific subpopulations or geographic areas that may present distinct benefit-risk profiles. Subpopulations and geographic areas that may present distinct benefit-risk profiles include, but are not limited to, pregnant women, individuals with a history of SUD/OUD or other mental health conditions, and geographic areas with high rates of unemployment or SUD/OUD.¹³²

The NAS report makes other recommendations regarding post-marketing surveillance and reporting that should be adopted by the FDA. The ASPPH Task Force also believes that any master settlement agreement should put stringent limitations on the marketing of opioids by manufacturers, limitations that extend well beyond those currently available under the statutes and regulations governing the FDA.

Naloxone, which is sold under the brand name Narcan®, among others, is a medication that effectively blocks the effects of opioids, especially in overdose situations. Although vials of naloxone are modestly priced, the cost for a package of two auto-injectors in the U.S. skyrocketed in 2016.¹³³ The FDA should take immediate steps to approve an affordable, accessible form of naloxone that can be sold over the counter. The availability of reasonably priced naloxone can save many additional lives.

The ASPPH Task Force urges the FDA to more effectively impose post-market requirements on opioid manufacturers. The FDA should mandate that manufacturers develop Risk Evaluation and Mitigation Strategies (REMS) to ensure that the benefits of a specific opioid drug outweigh the risks. While REMS often target prescribing and dispensing practices, in the case of opioids they should be inclusive of every aspect of the supply, delivery, and use continuum. Drug manufacturers are responsible for ensuring that REMS requirements are met. Given the track record of the opioid industry, the FDA should monitor REMS compliance carefully.

U.S. Congress

Since 2000, Congress has passed several major bills to address the opioid crisis. Dozens of separate initiatives have been enacted into law and funded through the appropriations process. Many of these initiatives focused on treatment expansion and supply interdiction.

Going forward, the Task Force urges Congress to consider new and more comprehensive legislation to address the opioid epidemic in a more systematic and comprehensive fashion and to ensure that those with OUD receive a full range of services that will improve their chances of managing the chronic disease of drug addiction. The Task Force believes that the Ryan White HIV/AIDS Program provides a useful model that should be replicated for those with OUD. The Ryan White program is a comprehensive system of HIV primary medical care, essential support services, and medications for low-income people living with HIV who are underinsured or uninsured and underserved. The program funds states, cities, counties, and local community-based organizations to provide care and treatment services to people living with HIV, both to improve health outcomes and reduce HIV transmission among hard-to-reach populations. Moreover, it funds provider education and specialized youth and pediatric efforts.

The Task Force urges Congress to consider new and more comprehensive legislation to address the opioid epidemic in a more systematic and comprehensive fashion and to ensure that those with OUD receive a full range of services that will improve their chances of managing the chronic disease of drug addiction.

Each year, more than half of people living with diagnosed HIV in the United States receive services through the Ryan White HIV/AIDS Program, which is managed by HHS's Health Resources and Services Administration (HRSA). Now almost 30 years old, the Ryan White HIV/AIDS Program has played a critical role in the United States' public health response to HIV. The program serves as an important source of ongoing access to HIV medication that can enable people living with HIV to live close to normal lifespans. In 2017, 85.9 percent of Ryan White HIV/AIDS Program clients were virally suppressed, exceeding the national average of 59.8 percent.²³ The Task Force believes that a similar program targeted to patients with OUD could produce similar results.

Another critical need is the modernization and adequate resourcing of various data and sentinel surveillance programs. The Drug Abuse Warning Network and the Arrestee Drug Abuse Monitoring program are important sources of data on abuse trends. Both need to be enhanced and provided with adequate funding. Where appropriate, states and communities should be mandated to use available reporting databases or face sanctions, such as the denial of non-patient-related federal resources.

Further, it is crucial to modernize the ability of care providers to prescribe buprenorphine. The Drug Addiction Treatment Act of 2000 expanded the clinical settings in which medication-assisted opioid dependency treatment can be offered. Under the statute, qualified physicians are permitted to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications (medications that have a lower risk for abuse, like buprenorphine) in settings other than an opioid treatment program. Broad areas of the country, especially rural

areas, still face a critical shortage of clinicians able to provide medication-assisted treatment for people diagnosed with OUD.

The Task Force calls on Congress to end the X waiver program that regulates physicians who choose to practice opioid dependency treatment. To make MOUD widely available, we must expand the number of physicians and others with the ability to assist those with OUD. Training in MOUD should be an essential part of the graduate and post-graduate (or continuing) education of all health professionals. Access to MOUD must be more readily available to serve all of those with OUD who are seeking treatment. The current regulatory hurdles are particularly harmful in rural areas where opioid treatment programs are not readily available. Primary care physicians will remain key providers of MOUD and they must be empowered to serve their patients in need.

Similarly, the current statutes and regulations on access to methadone should be updated. The distribution of methadone at properly equipped and trained pharmacies should be authorized and encouraged. The Task Force believes that pharmacists can serve as an important gateway to treatment. With proper training and monitoring, pharmacists in many states—especially in rural areas—could be key initial providers of MOUD. A well-designed and evaluated demonstration project to empower rural pharmacists to provide MOUD should be sponsored by relevant federal agencies.

Harm reduction strategies to address the opioid crisis are often controversial, even though many such strategies are proven to reduce overdose deaths and to accelerate access to treatment. The lifting of the legislative ban on the funding of syringe exchange programs has been a huge success in mitigating the other consequences of opioid use, such as AIDS/HIV and hepatitis C. It is now time for Congress to end the legislative prohibition on the purchase of syringes with federal funds. This provision is an annual rider to the Labor-HHS-Education appropriations bill. It is no longer appropriate or in the public interest.

Harm reduction strategies to address the opioid crisis are often controversial, even though many such strategies are proven to reduce overdose deaths and to accelerate access to treatment.

The Task Force also calls on Congress to support the availability of supervised consumption sites. Evidence from around the world suggests that supervised consumption sites help save lives, offer access to necessary services, and, more generally, provide support to people who abuse drugs. Providing evidence-based services will protect and improve the lives of people who use drugs and their families and communities. The best available evidence indicates that such sites provide critical individual and community health benefits with no evidence of increases in crime or drug use.

Congress should ensure that federal healthcare plans and services cover a full range of alternative pain management programs, including physical therapy and behavioral health. Medicare is testing payments for treating chronic lower back pain with alternative approaches. Based on the results of this demonstration, the HHS Centers for Medicare and Medicaid Services should consider expanding such an approach.

Lastly, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) have critical roles to play in addressing the opioid crisis. NIH's research portfolio regarding opioids should include

studies on the factors that make people and communities vulnerable to opioid misuse and addiction. The CDC's leadership in preventing OUD also is critical, both at the federal level and through its support of state, local, territorial and tribal health agencies. In addition, the CDC should fund prevention science initiatives by extramural researchers that will enhance our understanding of the factors that contribute to addiction and that will enhance prevention efforts. Congress and the administration should ensure that NIH, CDC, and other Public Health Service agencies have adequate personnel and fiscal resources to meet these critical responsibilities.

Opioid Manufacturers and Distributors

The opioid crisis can be directly tied to practices adopted and encouraged by opioid manufacturers and distributors. As such, the industry's credibility is near zero and major changes in its practices are essential.

As part of a master settlement agreement, the Task Force urges the industry to voluntarily end all lobbying and marketing activities related to opioids and other drugs of potential abuse. The Task Force urges the industry to voluntarily end the marketing of opioid antagonists to the judicial, law enforcement, and corrections entities at the federal, state, and local levels until such medications are proven to be similar to other forms of MOUD in terms of retention.

As mentioned earlier, we also call on the opioid manufacturing and distribution industries to agree to fund aggressive, independent campaigns aimed at educating the public about the risk of opioids and the availability of treatment options.

X. Conclusion

Swift, decisive, and far-reaching action is required to curtail and ameliorate the damage the opioid epidemic has wrought on our country. Experts predict that without strong efforts to mitigate the problem the annual number of opioid overdose deaths will reach 82,000 in the year 2025, bringing the total death toll to 700,000 over the 10-year period from 2016-2025.¹³⁴ Governments, industry, academia, health care professionals, and other sectors must join together, harnessing all available resources to fight the epidemic and reduce its harms. Advocacy, analysis, education, research, evaluation and deep community engagement are needed to understand the causes and abate the effects of opioid use disorder.

In offering the recommendations contained in this document, ASPPH underscores the importance of a public health science approach to combating the opioid epidemic. Many other stakeholders, including other public health and medical organizations, also have made recommendations complementary to the ones herein that are equally worthy of consideration. ASPPH stands ready to serve as a partner and resource, to federal and state policymakers and legislators, as well as to other concerned parties and organizations, in collaborative action to combat the opioid epidemic by bringing science to bear to save lives and reduce harm.

Appendix A: Task Force Members and Staff

Chair

Robert P. Pack, PhD, MPH

Associate Dean for Academic Affairs and
Professor of Community and Behavioral Health
East Tennessee State University College of Public Health

Members

Caleb J. Banta-Green, PhD, MPH, MSW

Principal Research Scientist, Alcohol and Drug Abuse Institute
Affiliate Associate Professor
School of Public Health, University of Washington

Donald S. Burke, MD

Dean (until July 1, 2019) and Professor
University of Pittsburgh Graduate School of Public Health

Hannah Cooper, ScD, ScM

Rollins Chair in Substance Use Disorders
Vice Chair, Behavioral Sciences/Health Education
Rollins School of Public Health at Emory University

Judith Feinberg, MD

Professor of Behavioral Medicine & Psychiatry and
Medicine/Infectious Diseases
Vice Chair for Research, Department of Medicine
West Virginia University School of Medicine

Cheryl G. Heaton, DrPH, MPA

Dean
New York University College of Global Public Health

Kimberly A. Horn, EdD

Research Professor, and
Director, Opioid Research Consortium of Central Appalachia
Virginia Tech Carilion Research Institute

Andrew Kolodny, MD

Co-Director, Opioid Policy Research, Institute for Behavioral
Health, Schneider Institutes for Health Policy, Heller School for
Social Policy and Management
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Associate Professor of Epidemiology
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Sten H. Vermund, MD, PhD

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Appendix B: Biographies of Task Force Members

Robert Pack, PhD, MPH, Chair

Dr. Pack is Professor of Community and Behavioral Health, Associate Dean for Academic Affairs in the College of Public Health at East Tennessee State University, Executive Director of the ETSU Center for Prescription Drug Abuse Prevention and Treatment and Co-Director of the Opioids Research Consortium of Central Appalachia (ORCA). The Center grew out of a university and community collaborative started in 2012 to address the regional opioid abuse problem. Funding sources for the Center include NIDA, PCORI, the State of Tennessee and various foundations. In 2018 the ETSU Center won the United States Public Health Service award for Excellence in Interprofessional Education Collaboration. Dr. Pack serves on the boards of One Tennessee Health, A Step Ahead Foundation-Tri-Cities, as Chairman of the Board of Directors of Overmountain Recovery, and is on the Appalachian Regional Commission Substance Abuse Advisory Council.

Caleb J. Banta-Green, PhD, MPH, MSW

Dr. Banta-Green is Principal Research Scientist at the Alcohol & Drug Abuse Institute, University of Washington. He is an affiliate associate professor at the School of Public Health, Department of Health Services and is Affiliate Faculty at the Harborview Injury Prevention and Research Center. He conducts research on opioid use disorder and overdose interventions. He also provides technical assistance and evaluation services for public health and safety interventions including the website www.stopoverdose.org and for multiple Federal Grants awarded to WA State agencies by SAMHSA and CDC. He is also an epidemiologist and reports drug trends across Washington State, with data available online <http://adai.uw.edu/wadata/>, has been the Seattle area representative to the National Institute on Drug Abuse's drug epidemiology workgroup since 2001, and partners with state and local agencies on drug epidemiology tracking and reporting. Dr. Banta-Green has an MSW, an MPH, and a PhD in Health Services Research from the School of Public Health, all from the University of Washington. He serves on several local and state workgroups and committees related to epidemiology and interventions for opioid related problems. He served as senior science advisor for the Office of National Drug Control Policy in the Executive Office of the President in 2012.

Donald S. Burke, MD

Dr. Burke is the former Dean of the Graduate School of Public Health and the Jonas Salk Chair in Population Health at the University of Pittsburgh. A native of Cleveland, Ohio, Dr. Burke received his BA from Western Reserve University (1967) and his MD from Harvard Medical School (1971). He has studied prevention and control of infectious diseases of global concern. He has lived six years in Thailand, worked extensively in Cameroon, and conducted collaborative vaccine and epidemiology studies in India, China, South Africa, and other countries. He served 23 years as an active duty officer at the Walter Reed Army Institute of Research, retiring at the rank of Colonel. He then served 9 years as a professor at the Johns Hopkins Bloomberg School of Public Health. He joined the University of Pittsburgh in 2006 where he founded the Pitt Public Health Dynamics Laboratory, an academic team that develops computational models and simulations of epidemics and uses these simulations to evaluate prevention and control strategies. He now leads a Pitt Public Health school-wide initiative aimed at control of the opioid epidemic. Dr. Burke has authored or co-authored more than 300 publications. He was the recipient of the prestigious 2018 John Snow Award from the American Public Health Association.

Hannah LF Cooper, ScD, ScM

Dr. Cooper holds the Rollins Chair in Substance Use Disorders at Emory University's Rollins School of Public Health, where she serves as the Co-Director of the Emory Center for AIDS Research's Prevention Science Core and as Vice Chair of the Department of Behavioral Sciences and Health Education. Trained at the Harvard School of Public Health, Dr. Cooper has extensive expertise in studying harm reduction strategies and structural factors (e.g., policies) that affect vulnerability to HIV, HCV, overdoses, endocarditis, and other drug-related harms among people who are actively misusing drugs. Dr. Cooper is currently Principal Investigator on five NIDA-funded grants on these topics. In her CARE2HOPE project (UG3 NA044798), for example, Dr. Cooper is partnering with community coalitions in each of 12 rural Kentucky counties to (1) conduct needs assessments of the local opioid epidemic in each county; (2) select interventions based on these assessments' results; and (3) implement a stepped-wedge community randomized trial to test the impact of these interventions. Dr. Cooper is also leading an implementation science study of the new syringe service programs that have opened up in these rural Kentucky counties, a project that builds on her extensive research on syringe service programs in urban areas. She has served on several federal panels, including the NIH's "Cutting Edge Science Meeting Series to End the Opioid Crisis: Contributions of Social and Behavioral Research to Addressing the Opioid Crisis," and the CDC's "Think Tank on the Social Determinants of Health" for the State, Tribal, Local, and Territorial Office within the CDC Director's Office.

Judith Feinberg, MD

In 2005, Dr. Feinberg was the first physician in metropolitan Cincinnati to recognize that opioid injection drug use had emerged as a health threat, based on increased admissions for infective endocarditis. She became involved in harm reduction efforts and, in 2014, after a nine-year effort, she established Ohio's third syringe exchange and its first true syringe services program, the Cincinnati Exchange Project (CEP). Conceived as a broad public health initiative, CEP not only exchanges sterile syringes for used ones, but also provides many other services: clean injection materials (cottons, cookers, etc.) to prevent hepatitis C; overdose prevention education and naloxone to reverse overdoses; condoms; safer sex and safer injection education; on-site rapid testing for HIV and hepatitis C; enrolling clients in expanded Medicaid through the Affordable Care Act; referral and linkage to drug treatment programs, medical and mental health care, and social services as desired. Through the use of peer recovery coaches, the CEP was successful in linking 10% of its clients to addiction treatment. West Virginia has the highest rates of acute hepatitis B, Neonatal Abstinence Syndrome, and overdose deaths in the U.S. and the 2nd highest rate of acute hepatitis C. After a long career in HIV/AIDS, she came to WVU in 2015 to focus on ending these opioid-related epidemics at their epicenter. As Professor of Behavioral Medicine & Psychiatry and Professor of Medicine/Infectious Diseases, she is working hard to turn the tide on opioid misuse and opioid-related epidemics.

Cheryl G. Heaton, DrPH, MPA

Dr. Heaton is the Dean of the College of Global Public Health (GPH) at New York University (NYU), Director of the Global Institute of Public Health, and a Professor of Public Health. Prior to this appointment, Dr. Heaton served as President and Chief Executive Officer of Legacy (now Truth Initiative®), the leading national foundation dedicated to tobacco control. During her 14-year tenure with the foundation, she guided the highly acclaimed, national youth tobacco prevention counter-marketing campaign, truth®, which has been credited in part with reducing youth smoking prevalence to record lows. Prior to joining Legacy, Dr. Heaton held numerous roles at Columbia University, including Associate Dean for Clinical Administration and Assistant Vice President of the Health Sciences, Chairman of Sociomedical Sciences, and Associate Dean of the Mailman

School of Public Health. She has authored over 120 peer-reviewed articles and special reports, and has been awarded multiple grants in AIDS, tobacco control and higher education. Dr. Healton also led numerous grant efforts focused on AIDS, substance-use, and tobacco. She was the founding chair of the Public Health Practice Council of the Association of Schools of Public Health and is an active member of the public health community; serving on the National Board of Public Health Examiners, Lung Cancer Alliance, Action on Smoking and Health, and Americans for Non Smokers' Rights. Dr. Healton received her DrPH from Columbia University's School of Public Health (with distinction) and an MPA in Public Administration from New York University in Health Policy and Planning.

Kimberly A. Horn, EdD, MSW

Dr. Horn is a scientist in the Virginia Tech Carilion Fralin Biomedical Research Institute and a research professor in the Department of Population Health Sciences at Virginia Tech. Arriving from George Washington University, where she was the research dean in the School of Public Health, Dr. Horn is a nationally recognized research leader, scholar, and innovator. Dr. Horn has a diverse research funding portfolio from federal, state, and private agencies investigating tobacco and other substance use disorders. Almost two decades of continuous federal funding has afforded her the opportunity to develop an internationally recognized program of research in youth and young adult tobacco control. A significant part of that program is the Not On Tobacco (N - O - T) teen smoking cessation program. N - O - T was formally adopted by the American Lung Association (ALA) in 1998 and continues today across the U.S. helping thousands of youth stop using tobacco. N - O - T is cited as the most widely used teen cessation program in the U.S., and received several national designations, including a Substance Abuse and Mental Health Administration evidence-based Model Program, a National Cancer Institute Research Tested Intervention Program, Centers for Disease Control and Prevention Adoptable Program, and an Office of Juvenile Justice and Delinquency Prevention Model Program. At Virginia Tech, Dr. Horn is continuing to focus on substance abuse prevention and innovations to address the opioid crisis in central Appalachia. To that end, she is the founding director of the Opioid Research Consortium of Central Appalachia (ORCA), and PI of a new PCORI grant award to jump-start the ORCA initiative.

Andrew Kolodny, MD

Dr. Kolodny has been working on the opioid addiction epidemic for the past 16 years as an addiction treatment specialist, researcher, public health official and advocate. He is Co-Director of the Opioid Policy Research Collaborative at the Heller School for Social Policy and Management at Brandeis University and teaches about the opioid crisis at Columbia University's Mailman School of Public Health. He is also the executive director of Physicians for Responsible Opioid Prescribing, an organization with a mission to reduce morbidity and mortality caused by overprescribing of opioid analgesics. Dr. Kolodny previously served as Chief Medical Officer for Phoenix House, a national nonprofit addiction treatment agency, and Chair of Psychiatry at Maimonides Medical Center in New York City. Dr. Kolodny has a long-standing interest in public health. He began his career working for the New York City Department of Health and Mental Hygiene in the Office of the Executive Deputy Commissioner. For New York City, he helped develop and implement multiple programs to improve the health of New Yorkers and save lives, including city-wide buprenorphine programs, naloxone overdose prevention programs and emergency room-based screening, brief intervention and referral to treatment (SBIRT) programs for drug and alcohol misuse.

Brandon D.L. Marshall, PhD

Dr. Marshall is an Associate Professor of Epidemiology at the Brown University School of Public Health. He received a PhD in epidemiology from the School of Population and Public Health at the University of British Columbia. In 2011, he completed postdoctoral training at the Columbia University Mailman School of Public Health. Broadly, Dr. Marshall's research focuses on substance use epidemiology, infectious diseases, and the social, environmental, and structural determinants of health of drug-using populations. He is the Principal Investigator of multiple NIH- and CDC-funded studies that seek to improve the health of people who use drugs. He has published more than 150 scientific publications. As the Scientific Director of PreventOverdoseRI, Rhode Island's drug overdose surveillance and information dashboard, he works closely with the Rhode Island Department of Health to track, measure, and evaluate efforts to address the state's opioid overdose epidemic. He serves as an expert advisor to Governor Raimondo's Overdose Prevention and Intervention Task Force. He has received numerous accolades and awards for his research, including the Henry Meritt Wriston Fellowship from Brown University in 2015, and the 2016 Brian MacMahon Early Career Award from the Society for Epidemiologic Research.

William C. Miller, MD, PhD, MPH

Dr. Miller is Professor and Chair in the Division of Epidemiology, College of Public Health at The Ohio State University. Dr. Miller is an infectious diseases epidemiologist with primary expertise in sexually transmitted diseases, HIV infection, and substance use. His work has addressed STD and HIV epidemiology broadly, including partner services, surveillance, spatial analyses, and diagnostic test evaluation. He is the protocol chair for HIV Prevention Trials Network (HPTN) 074, a study examining approaches to engaging people who inject drugs in HIV care to prevent transmission to uninfected injection partners. He is also the PI of a NIDA-funded UG3 award to address the opioid crisis in Ohio. Dr. Miller is the editor-in-chief of the journal, *Sexually Transmitted Diseases*, and associate editor of *Epidemiology*.

Brendan Saloner, PhD

Dr. Saloner is an Assistant Professor in the Department of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health. His research focuses on policy issues related to access and quality of care for people with behavioral health disorders, with a special focus on opioid use disorders. Dr. Saloner has investigated the impact of federal and state policies regarding insurance coverage and benefit design related to substance use disorders on access to care and outcomes related to treatment. He holds an early career award from the National Institute on Drug Abuse to study the effects of Medicaid program design on treatment for opioid use disorder. He has also published widely on the changing financing and delivery of behavioral health treatment under the Affordable Care Act. He co-leads the Addiction and Overdose workgroup of the Bloomberg American Health Initiative. He holds a doctorate in Health Policy from Harvard University and completed the Robert Wood Johnson Health and Society Scholars Program at the University of Pennsylvania.

Michael D. Stein, MD

Dr. Stein is Professor and Chair of the Department of Health Law, Policy & Management at the Boston University School of Public Health. He is an internist and has been a leader in substance use research and teaching since the early 1990's. Dr. Stein has been Principal Investigator of more than a dozen NIH-funded clinical trials involving substance-using populations over the past decade. Dr. Stein's work has focused on combined biomedical and psychosocial treatment development for substance users including persons with opioid use disorders, drug injectors, alcohol, cocaine and marijuana users. His current work is related to opioid use disorder involves linkage of persons with opioid use disorders to buprenorphine, treating opioid

dependence and pain with yoga, examining neuroimaging predictors of relapse during buprenorphine treatment, and an evaluation of the policy of civil commitment for persons who use opioids. Dr. Stein received a NIDA Mid-Career Mentorship Award (K24); many of his more than 350 publications have been with current or past trainees. He is Executive Editor of Public Health Post, a popular website that produces original journalism, viewpoints, and research reviews on matters of population health. With Dr. Sandro Galea, he writes the weekly newsletter, “The Public’s Health.” He is the author of the award-winning book, *The Addict: One Patient, One Doctor, One Year*.

Sten H. Vermund, MD, PhD

Dr. Vermund is Dean of the Yale School of Public Health, the Anna M.R. Lauder Professor of Public Health, and Professor of Pediatrics at the Yale School of Medicine. As an infectious disease epidemiologist and pediatrician focused on diseases of low and middle-income countries, and on health disparities in the U.S., his research has focused on the interface of HIV prevention with reproductive health and substance use, HIV health care access, adolescent medicine, and prevention of mother-to-child HIV transmission. Dr. Vermund is co-author of over 600 papers and chapters with his students and colleagues and has founded two successful non-governmental organizations: Centre for Infectious Disease Research in Zambia (CIDRZ) and Friends in Global Health (FGH) in Mozambique and Nigeria. He is a member of the National Academy of Medicine and a Fellow of the AAAS.

April M. Young, PhD, MPH

Dr. Young is an Associate Professor in the Department of Epidemiology at the University of Kentucky College of Public Health and Faculty Associate with the University of Kentucky Center on Drug and Alcohol Research. Dr. Young completed doctoral training at Emory University’s Rollins School of Public Health and for nearly ten years has researched the disproportionate burden of opioid use and related harms in rural Central Appalachia. She has authored or co-authored over 50 publications, most of which focus on substance use and related harms. She has led five federally funded studies focused on issues related to substance use, including a National Rural Opioid Initiative study funded by a cooperative agreement from NIH, CDC, SAMHSA, and the Appalachian Regional Commission. She is also among the lead co-investigators on the HEALing Communities Study in Kentucky, a historic initiative funded by NIH and SAMHSA to reduce opioid related deaths by 40 percent over three years in severely impacted communities.

Appendix C: Conflict of Interest Disclosures

It is the policy of the Association of Schools and Programs of Public Health (ASPPH) to promote balance, independence, objectivity, and scientific rigor in all its activities through the disclosure of financial and other interests and the management of actual or potential conflicts.

Before the Task Force began its deliberations, the panel agreed to develop and complete a conflict-of-interest disclosure form. The form developed by the panel focused on:

- Significant financial interests in entities engaged in the production, distribution or marketing of opioid products or treatments;
- Relationship with parties involved in opioid litigation; and
- Other relationships (formal or informal), funding sources, service as an expert witness, or professional or personal engagements that should be disclosed.

Given the charge of the Task Force, disclosure of relevant interests is essential. No disclosures were deemed to require a management plan. All disclosure filings were made available to all other Task Force members via a shared network drive. The relevant disclosures reported by Task Force members are:

- Dr. Caleb Banta-Green reported that he has received funding from various government agencies and private foundations with an interest in addressing the opioid crisis. He also reports having had an intergovernmental personnel agreement in 2012 when he had a temporary assignment to work at the Office of National Drug Control Policy, Executive Office of the President. He has never received funding from pharmaceutical or opioid manufacturing companies or other for-profit entities.
- Dr. Donald Burke is a co-founder, President and Chairman of the Board of Epistemix, Inc, a startup company that creates and implements software to simulate epidemics and methods to control them. The company does not currently perform any work on the opioid epidemic, but it may do so in the future.
- Dr. Andrew Kolodny reported that he has received income for work as an expert witness for the state of Oklahoma in its case against opioid manufacturers and other cases involving opioids. He is also the Executive Director of Physicians for Responsible Opioid Prescribing.
- Dr. Robert Pack reported that 2004 and 2007 legal settlements between the West Virginia attorney general's office and Purdue Pharma resulted in the creation of a funding pool for initiatives to discourage drug abuse. Dr. Pack managed a small research team at the West Virginia University School of Medicine that received funds from the pool to establish and evaluate the "West Virginia Prescription Drug Abuse Quitline." Dr. Pack's involvement in the project ended when he transitioned to ETSU in 2008.
- Dr. Brendon Saloner reported that he has a nondisclosure agreement with Monument Analytics, a litigation consulting research firm run by a colleague (Caleb Alexander). The agreement allows him to discuss the firm's work for clients involved in the opioid litigation. However, Dr. Saloner is not accepting any consulting income from either the firm or litigants.

- Dr. April Young reported that she earlier was a member of the research staff on a grant funded by Purdue Pharma and is an author of two publications on which Purdue Pharma is listed as a funder (<https://doi.org/10.1186/1477-7517-7-24>; <https://doi.org/10.3109/00952990.2011.643971>).

In addition to the above disclosures, two other disclosures of note are:

- The Association of Schools and Programs of Public Health has received no support from opioid manufacturers or distributors. Similarly, the staff of ASPPH has received no remuneration or other support from opioid manufacturers or distributors.
- The disclosure documents completed by Task Force members did not inquire about institutional support received by ASPPH member schools and programs by opioid manufacturers or distributors, or from the families associated with such firms. Some member schools and programs have acknowledged receiving such support in the past.

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